

An abstract geometric composition on a dark navy blue background. On the left, a vertical cream-colored bar is divided into four equal segments by three thin teal horizontal lines. Two small teal dots are positioned at the intersections of the first and second, and second and third horizontal lines. To the right of this bar, a large teal shape is composed of a trapezoid at the bottom, a rectangle in the middle, and a triangle at the top. A thin white vertical line runs down the center of the teal trapezoid, ending at a small teal circle at its top edge. The word "China" is written in a white, sans-serif font, centered horizontally and partially overlapping the cream bar and the teal shape.

China

China

Understanding the applicable framework

This chapter concerns mainland China, not automatically Hong Kong, Macao or Taiwan. Assess legal status, registration, activity, funding and overseas involvement.

The published RDPAC Code effective in 2023 addresses independence, company involvement and documentation (R&D-based Pharmaceutical Association Committee [RDPAC], 2023, art. 11).

What companies need to understand

Establish whether the partner is a registered organisation, a hosted project or an informal network and who can contract, receive funds and accept responsibility. Legal registration differs from permission to fundraise publicly. Public fundraising requires the relevant qualification; an organisation's name and registration alone are insufficient (Ministry of Civil Affairs, 2024, art. 3).

Overseas organisations

The Overseas NGO Law establishes registration or temporary-activity filing arrangements for covered organisations and regulates cooperation and funding (Law on Administration of Activities of Overseas Nongovernmental Organizations in Mainland China, 2016, arts. 9, 16–22).

Map all roles and funds before announcement. Working through a local entity or agency does not automatically remove obligations. Equally, this law should not automatically be applied to every overseas commercial company.

Personal information

The PIPL treats medical and health information as sensitive and addresses necessity, safeguards and separate consent, subject to the applicable legal framework (Personal Information Protection Law of the People's Republic of China, 2021, arts. 28–30).

Decide storage, access and cross-border requirements before choosing platforms. Global participation does not establish blanket permission to upload health information overseas. Consider local summaries.

Regulatory and development participation

CDE's 2022 trial guidance concerns organised patient input into development, not an automatic entitlement to regulatory decisions (Center for Drug Evaluation [CDE China], 2022).

Distinguish development advice, research evidence and authority participation. Explain influence and approvals and avoid promises of treatment access or adoption of recommendations.

Practical example and local checks

For an international alliance's workshop, assess overseas activity, local partner authority, filing or registration and funds before recruitment. Agree support, data and publication, with project-specific industry and transfer assessment rather than unchanged global terms.